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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,551	05/20/2004	Jeffrey Moscow	50229-435	7209

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,551	MOSCOW ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a method of screening candidate substances of the OCT6 transporter, classified in class 435, subclass 4.

II. Claims 5-7, drawn to a method of screening potential anti-leukemia agents comprising determining viability of a mammalian cell line which expresses OCT6 incubated in the presence of the test compound and identifying the test compound as a potential anti-leukemia agent if the compound causes cell death, classified in class 435, subclass 4.

III. Claims 8-9, drawn to a test kit comprising a mammalian cell line overexpressing OCT6 and an antibody or compound which does not react with OCT6, classified in class 435, subclass 325.

IV. Claims 10-20, drawn to an immunogenic composition comprising a substrate that binds selectively to an OCT6 transporter, classified in class 530, subclass 387.1, for example.

V. Claims 21-25, drawn to a method of treating a hematological malignancy comprising administering an OCT6 substrate which binds specifically or selectively to the OCT6 protein, classified in class 424, subclass 130.1, for example.

VI. Claims 26-40, drawn to a method for the treatment of leukemia or a method of impairing a leukemia cell blast comprising administering a substrate that selectively binds to the OCT6 transporter gene, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-II and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions I-II and V-VI are different methods because they require different ingredients, process steps, and endpoints. Groups I-II and V-VI are different methods requiring different method steps, wherein each is not required, one for another. For example, Group I requires search and consideration of screening candidate substances of the OCT6 transporter by determining

whether the test agent is a substrate for OCT6, which is not required by the other inventions. Group II requires search and consideration of screening potential anti-leukemia agents comprising determining viability of a mammalian cell line which expresses OCT6 incubated in the presence of the test compound and identifying the test compound as a potential anti-leukemia agent if the compound causes cell death, which is not required by the other inventions. Group V requires search and consideration of administering an OCT6 substrate which binds specifically or selectively to the OCT6 protein, which is not required by the other inventions. Group VI requires search and consideration of administering a substrate that selectively binds to the OCT6 transporter gene, which is not required by the other inventions. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-II and V-VI have a separate status in the art as shown by their separate search requirements. As such, it would be burdensome to search the inventions of Groups I-II and V-VI together.

b. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups III-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the mammalian cell line overexpressing OCT6 and the antibody/compound which does not react with OCT6 of Group III have a different structure and function than the substrate that binds selectively to an OCT6 transporter of Group IV and may be used in materially different methods.

Additionally, searching the inventions of Groups III-IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications and separate search requirements. The technical literature searches for the inventions of Groups III-IV are not coextensive.

c. Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the cell line overexpressing OCT6 and the control antibody can be used in materially different methods, such as cell growth and survival assays.

d. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the OCT6 substrate that binds the OCT6 transporter of Group IV can be used in materially different methods, such as diagnostic assays or cell culture assays.

e. Inventions IV and I/II/VI are unrelated because the product of Group IV is not used or otherwise involved in the processes of Groups I/II/VI.

f. Inventions III and II/V/VI are unrelated because the product of Group III is not used or otherwise involved in the processes of Groups I/II/VI.

2. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), as well as have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species:

A detectable substance or label:

a. extrinsically activatable enzymes

b. prosthetic groups

c. fluorescent materials

d. luminescent/bioluminescent materials

e. radioactive materials

f. positron emitting metals using various positron emitting tomographies

g. nonradioactive paramagnetic metal ions

h. immunogenic tag peptide sequences

i. extrinsically activatable toxins

j. extrinsically activatable quenching agents

k. antibodies

The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for fluorescent labels may not result in relevant art with respect to labels with positron emitting metals using various positron emitting tomographies.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 and 8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. This application contains claims directed to the following patentably distinct species: The substrate/compound that selectively binds the OCT6 transporter protein, wherein the substrate/compound is:

l. a cytotoxic agent

m. is coupled with a cytotoxic agent

The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for a cytotoxic agent may not result in relevant art with respect to compounds labeled with a cytotoxic agent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 16-17, 21, 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
21 February 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER